Medicines Australia –
Application for revocation of authorisation AA1000486 and the substitution of authorisation AA1000579
Interim authorisation decision
29 September 2021

Decision

1. The Australian Competition and Consumer Commission (the **ACCC**) has decided to suspend the operation of authorisation AA1000486 and grant conditional interim authorisation in substitution for the suspended authorisation. The conditional interim authorisation is in respect of application AA1000579 lodged by Medicines Australia (**MA**) on 17 September 2021.
2. MA has applied for authorisation on behalf of itself and its members, the Generic and Biosimilar Medicines Association (**GBMA**) and its members, and other entities that have been or in the future will be notified by MA to the ACCC (the **MA/GBMA Working Group**).
3. The ACCC has granted conditional interim authorisation, in relation to Division 1 of Part IV of *the Competition and Consumer Act 2010* (Cth) (the **Act**) and section 45 of the Act, to enable the MA/GBMA Working Group to give effect to the conduct described at paragraphs 12 and 13 below. Broadly, interim authorisation is granted to enable the MA/GBMA Working Group to implement a coordinated strategy at the request of the Federal Government and/or a Federal Government Agency to address shortages in the supply of:
    i. prescription-only medicines that are critical to patient health, including medicines used to treat patients suffering from the symptoms of COVID-19 (**Critical Medicines**); and
    ii. devices or services that are supplied or administered with Critical Medicines, and therefore essential to the efficacy and proper administration of Critical Medicines (**Critical Devices**).
4. Interim authorisation is granted with the condition set out in paragraph 23 below.
5. Interim authorisation commences immediately and remains in place until the date the ACCC's final determination comes into effect, the application for authorisation is withdrawn, or until the ACCC decides to revoke interim authorisation.

Background

6. MA represents the discovery-driven pharmaceutical industry in Australia. MA works in partnership with government, the Australian innovative medicines industry, consumer groups and health professionals to develop health and industry policy.
7. The GBMA is the national association representing generic and biosimilar medicine suppliers in Australia. Its members consist of companies that manufacture, supply and market pharmaceutical products in Australia, while its associate members provide consultation and services to the pharmaceutical and pharmacy industries.

The application for re-authorisation

8. On 17 September 2021, MA lodged an application for the revocation of authorisation AA1000486 (the **Existing Authorisation**) and the substitution of authorisation AA1000579 in its place (re-authorisation).
9. The Existing Authorisation was granted on 24 September 2020 and is due to expire on 30 September 2021.
10. The proposed conduct in the application for re-authorisation is narrower than the Existing Authorisation. Specifically, the conduct will only be engaged in by MA/GBMA Working Group members at the request of, rather than in consultation with, the Federal Government and/or a Federal Government Agency. Further, the application for re-authorisation does not seek authorisation for any conduct related to tendering.
11. MA has also requested changes to the conditions of re-authorisation. In particular, MA requests that it only be required to report to the ACCC on a monthly basis, or no later than 5 business days following a meeting of MA/GBMA Working Group members. The condition in the Existing Authorisation required fortnightly reporting. MA also requests the current government health agency tendering condition be removed because re-authorisation is not being sought for tendering conduct.

The Proposed Conduct

12. MA seeks re-authorisation to allow the MA/GBMA Working Group, at the request of the Federal Government and/or a Federal Government Agency, to implement a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices to address shortages in the supply of these products that arise as a result of COVID-19.
13. The specific conduct for which re-authorisation is sought includes:
    (a) sharing information regarding:
        (i) available stock and inventory levels
        (ii) likely quantities that can be obtained through existing supply channels
        (iii) new sources of supply and potential quantities
        (iv) opportunities to increase domestic manufacturing

        for Critical Medicines and Critical Devices
    (b) coordinating and allocating the fulfilment of orders and supply requests for Critical Medicines and Critical Devices between MA/GBMA Working Group members as suppliers
    (c) prioritising certain requests for supply for Critical Medicines and Critical Devices as nominated by the Federal Government, State and Territory Governments and relevant health authorities

    (together, paragraphs 12 and 13 form the **Proposed Conduct**).
14. MA seeks re-authorisation for 12 months. It does so having regard to the Australian Government's National Plan to transition Australia's National COVID-19 Response published on 31 July 2021.[1]
15. MA seeks re-authorisation in relation to Division 1 of Part IV of the Act, and section 45 of the Act (**Relevant Provisions**).

[1] https://www.pm.gov.au/media/national-cabinet-statement-10

The authorisation process

16. Authorisation provides protection from legal action for conduct that may otherwise breach the competition provisions of the Act. Broadly, the ACCC may grant authorisation if it is satisfied that the benefit to the public likely to result from the conduct outweighs any public detriment likely to result, including from a lessening of competition. The ACCC conducts a public consultation process to assist it to determine whether proposed conduct results in a net public benefit.
17. The power conferred upon the ACCC to authorise conduct is discretionary. In exercising that discretion, the ACCC may have regard to considerations relevant to the objectives of the Act.
18. The ACCC may specify conditions in an authorisation. The legal protection provided by an authorisation does not apply if any conditions are not complied with.

Interim authorisation

19. Section 91 of the Act allows the ACCC, where it considers it appropriate, to grant interim authorisation. This allows parties to engage in specified conduct without contravening the specified provisions of the Act while the ACCC is considering the substantive application.
20. MA requests interim authorisation because the Existing Authorisation is due to expire on 30 September 2021 and the ongoing and escalating challenges arising from the Delta variant of COVID-19 are likely to require MA/GBMA Working Group members to engage (on short notice) in the Proposed Conduct. Interim authorisation will enable the MA/GBMA Working Group to engage in a narrower form of the conduct than under the Existing Authorisation while the ACCC is considering the substantive application for re-authorisation.

Consultation

21. The ACCC has not conducted a public consultation process in respect of the request for interim authorisation. This is due to the need to provide ongoing authorisation, with a view to ensuring the continued supply of essential medicines and associated supplies, including those needed for the treatment of COVID-19 to Australians, and the compelling nature of the public benefits likely to result from the request for interim authorisation.
22. The ACCC will conduct a public consultation process on the substantive application for re-authorisation and will further examine the public benefits and detriments likely to result from the Proposed Conduct during that process. Details regarding how to make a submission will be available on the ACCC's authorisations public register.

Granting of conditional authorisation

23. Interim authorisation is granted in relation to the Relevant Provisions to the MA/GBMA Working Group for the Proposed Conduct with the condition that MA must:
    1. provide a report to the ACCC at the end of each month or within 5 business days of any meeting, discussion, development or decision between MA/GBMA Working Group members in relation to the Proposed Conduct, to be published on the ACCC's public register (subject to the ACCC deciding to exclude material from the register, as requested by MA) (the **Monthly Report**). The Monthly Report must report on any meetings, discussions, developments and decisions in relation to the Proposed Conduct. The Monthly Report must include, insofar as the following information has not already been provided in a previous Monthly Report:

a. material recommendations, if any, made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct

b. information regarding any meeting or discussion between two or more of the MA/GBMA Working Group members relating to the Proposed Conduct, including:

i. the attendees at the meeting or discussion

ii. the agenda items of the meeting or discussion that are related to the Proposed Conduct

iii. any minutes of the meeting or discussion relating to the Proposed Conduct

iv. an overview of topics discussed and any material decisions made that related to the Proposed Conduct

c. any changes to the MA/GBMA Working Group

2. provide the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct

3. meet with the ACCC to provide regular updates in relation to the Proposed Conduct, as requested by the ACCC.

24. This condition is largely the same as the condition of the Existing Authorisation, with minor changes as set out in paragraph 11 above.

Reasons for decision

25. In granting interim authorisation, the ACCC recognises the urgency of the request for interim authorisation given the upcoming expiry of the Existing Authorisation on 30 September 2021 and the need for the MA/GBMA Working Group to continue to give effect to the conduct while the ACCC considers the substantive application for re-authorisation.

26. The ACCC considers that it is unlikely that interim authorisation will have an ongoing anti-competitive impact. In particular:

(a) The Proposed Conduct will only be engaged in by MA/GBMA Working Group members at the request of the Federal Government and/or a Federal Government Agency.

(b) The Proposed Conduct is a temporary measure in response to the COVID-19 pandemic.

(c) The Proposed Conduct, and interim authorisation, only apply to arrangements and conduct for the purposes of implementing a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices in the circumstances of the COVID-19 pandemic.

(d) The Proposed Conduct is not compulsory and any participant can opt out of any information sharing arrangements or other authorised conduct.

(e) Pursuant to the condition outlined above, MA will notify the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including any material recommendations made by the MA/GBMA Working Group to the Federal Government and material decisions or arrangements it makes. A similar condition applied to the Existing Authorisation and MA provided regular reports to the ACCC that confirmed various discussions took place throughout the year between the Therapeutic Goods Administration (**TGA**) and suppliers in relation to the supply of certain medicines following the

identification of possible shortages or interruptions to supply chains. These discussions covered issues such as the possible supply issues, current stock levels and gaps or areas of potential coordination to resolve supply shortages for Critical Medicines.

(f) The Proposed Conduct will be undertaken in the context of broader coordination and communication by the MA/GBMA Working Group with relevant Government and regulatory bodies, including the TGA.

(g) The ACCC may review its decision to grant interim authorisation at any time, including in response to feedback as the Proposed Conduct is rolled out. If any persons, including relevant Government and regulatory bodies, have concerns with the way the MA/GBMA Working Group members are dealing with them during the period of interim authorisation, they are encouraged to advise the ACCC.

27. Further, the ACCC considers there are likely to be significant public benefits that result from the Proposed Conduct in the current circumstances, including enabling MA/GBMA Working Group members to, at the request of the Federal Government and/or a Federal Government Agency:

(a) coordinate discussions within the medicines supply chain to develop and implement strategies to ensure the continued supply of essential medicines and supplies to Australians

(b) provide more effective advice to governments and relevant health agencies regarding the supply of essential medicines and associated supplies including by identifying and addressing supply shortages and constraints, and

(c) maximise the efficient use of supply channels in this time of peak demand.

Reconsideration of interim authorisation

28. The ACCC may review a decision on interim authorisation at any time.

29. The ACCC's decision in relation to the interim authorisation should not be taken to be indicative of whether or not the final authorisation will be granted.